

CLAIMS

1. A spore genetically modified with genetic code comprising at least one genetic construct encoding an antigen and a spore coat protein as a
5 chimeric gene, said genetically modified spore having said antigen expressed as a fusion protein with said spore coat protein.
2. A spore as claimed in Claim 1 characterised in that the spore is of
10 *Bacillus* species.
3. A spore as claimed in Claim 1 or Claim 2 characterised in that the genetic construct comprises at least part of a spore coat protein gene and at least part of an antigen gene, in the form of a chimeric gene.
- 15 4. A spore as claimed in any one of the preceding Claims characterised in that the antigen gene is located at the 3' end of the spore coat protein gene.
- 20 5. A spore as claimed in any one of the preceding Claims characterised in that the genetic construct comprises a spore coat promoter at the 5' end of the chimeric gene.
6. A spore as claimed in any one of the preceding Claims characterised in that the antigen is at least one of tetanus toxin fragment
25 C or labile toxin B subunit.
7. A spore as claimed in any one of the preceding Claims characterised in that the spore coat protein is selected from the group consisting of *cotA*, *cotB*, *cotC*, *cotD*, *cotE*, *cotF*, *cotG*, *cotH*, *cotJA*,
30 *cotJC*, *cotM*, *cotSA*, *cotS*, *cotT*, *cotV*, *cotW*, *cotX*, *cotY* and *cotZ*.

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8. A spore as claimed in any one of the preceding Claims characterised in that the spore is heat inactivated that in use it does not germinate into a vegetative cell.

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9. A spore as defined in any one of the preceding Claims for use in treatment of a medical condition.

10. A composition comprising at least two different spores as defined in any one of the preceding Claims characterised in that said at least two different spores express at least two different antigens.

11. A composition as defined in Claim 10 characterised in that the composition further comprises a pharmaceutically acceptable excipient or carrier.

12. A composition comprising a spore as defined in any one of claims 1 to 9 in association with a pharmaceutically acceptable excipient or carrier.

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13. A composition as defined in any one of Claims 10 to 12 for use in treatment of a medical condition, preferably the medical condition is inflammation, pain, a hormonal imbalance and/or an intestinal disorder.

14. Use of a spore as defined in any one of claims 1 to 9 in the manufacture of a medicament for use in the treatment of a medical condition, preferably the medical condition is inflammation, pain, a hormonal imbalance and/or an intestinal disorder.

15. A method of medical treatment, which method comprises the steps of

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- a) administering a spore as defined in any one of claims 1 to 9 to a human or animal in need of medical treatment;
- b) said genetically modified spore eliciting an immune response for use in the prevention of a disease.

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16. A method as claimed in Claim 15 characterised in that the spore is administered orally, intra-nasally or rectally.

17. A method of producing a genetically modified spore, which method
10 comprises the steps;

producing genetic code comprising at least one genetic construct encoding an antigen and a spore coat protein as a chimeric gene;

15 using said at least one genetic construct to transform a vegetative mother cell;

inducing said transformed mother cell to sporulate; and

isolating the resulting genetically modified spores.

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